EU Declaration of Conformity (PPE)

CE & UKCA Certification to Regulation (EU) 2016/425

This Declaration of Conformity is issued under the sole responsibility of Kenex (Electro-Medical) Limited, the manufacturer of the below listed PPE category III products; and confirms that the requirements specified in Regulation (EU) 2016/425, relating to personal protection (against external ionising radiation equipment), have been achieved.

Notified Body SGS Fimko OY, Takomotie 8, FI-00380 Helsinki Finland performed an EU type-examination and issued certificate: F120/967318 and certified that the technical file and PPE details of the listed products are in accordance with Module B of Regulation (EU) 2016/425. A further certificate: F120/967474 also issued by SGS Fimko OY, confirms conformity based on the production process as required by Module D at Annex VIII of this standard. A certificate: GB120/967475 issued by UK Approved Body SGS (UK) Limited, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK, confirms that the QMS meets the requirements of Module D of Regulation (EU) 2016/425, REACH EC 1907/2006.

The listed products are in conformity with harmonised standards BS EN 61331-1 relating to the x-ray attenuating properties of flexible materials used, and to BS EN 61331-3 relating to x-ray protective clothing, and to Standards BS EN 13402-3 & BS EN ISO 13688 relating to the attributes of protective clothing. And BS EN ISO 14971:2019, BS EN ISO 15223-1:2021.

Kenex (Electro-Medical) Limited is certified as meeting the requirements of BS EN ISO 13485:2016+A11:2021 related to medical devices quality management systems. QA systems are audited by our Notified Body & UK Approved Body SGS Limited.

Kenex LytaType x-ray protective clothing including: -
model groups 903, 905, 907, 909, 910, 911, 915, 917, 919, 921, 951 and 953
Global Model Number (GMN) Basic UDI-DI: 50554494AXAB
GMDN: (Aprons) 38355, (Thyroid Collars) 38358.

EC REP

EU authorised representative: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.
Emergo Single Registration Number (SRN): NL-AR-000000116

CH REP

Swiss authorised representative: MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland.

Kenex Single Registration Number (SRN): GB-MF-000009022
Signed:

Paul Hunt, Managing Director
On behalf of Kenex (Electro-Medical) Limited
Place: Harlow, CM19 5QB, UK
Date: 25/03/2024

UK CA 0120 CE 0598

Kenex (Electro-Medical) Limited
Unit 17, RO24 Greenway, Harlow Business Park, Harlow, Essex CM19 5QB, England
T: +44 (0)1279 417241 F: +44 (0)1279 443749 E: kenex@kenex.co.uk www.kenex.co.uk